

Appln No. 10/806,906
Amdt date January 28, 2009
Reply to Office action of October 30, 2008

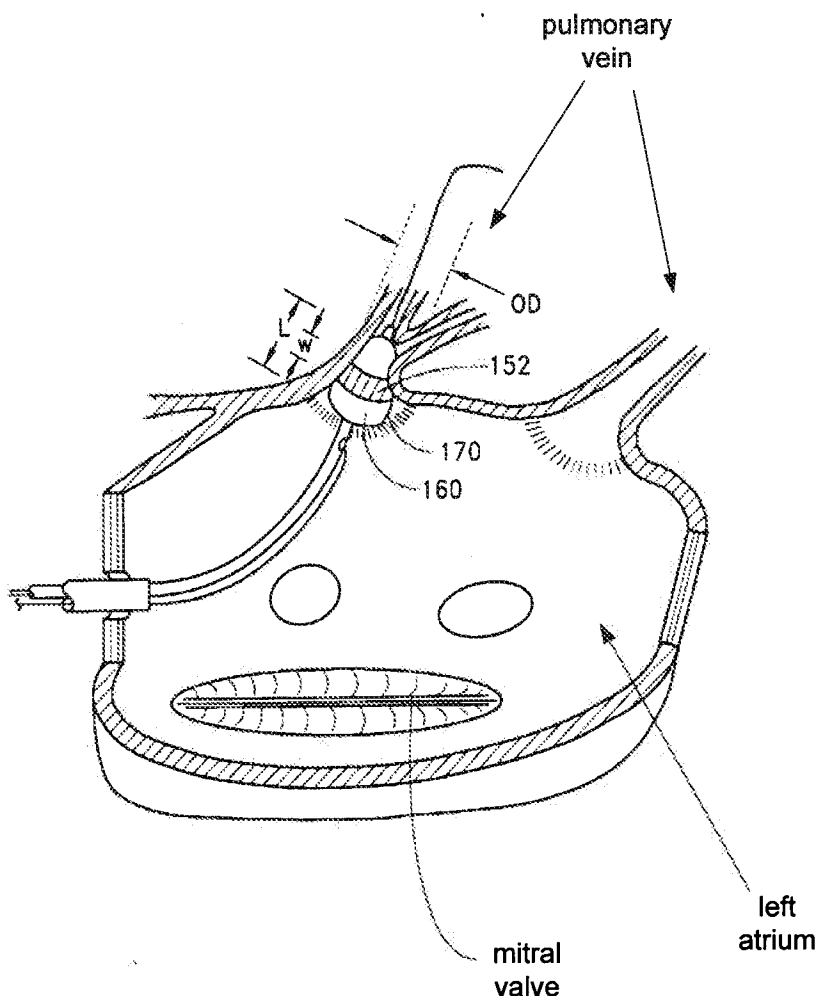
REMARKS/ARGUMENTS

Claims 1-37 are pending in the application.

Applicants' attorney, Saeid Mirsafian, conducted a telephone interview with Examiner Schillinger on January 22, 2009, to discuss the rejection of claims 1 and 19 over Diederich (6,117,101). Applicants' attorney argued that Diederich fails to teach or suggest several elements of claims 1 and 19. In particular Applicant's attorney argued that Diederich fails to teach or suggest manipulating the prosthesis to exert a compressor force on the mitral valve annulus, assessing mitral valve regurgitation in response to the monitoring step, and adjusting the prosthesis in a response to the assessing step. Applicants' attorney and the Examiner could not reach an agreement. The Examiner stated that Applicants should file a response to the Office action with the same arguments for consideration by the Examiner. Applicants would like to thank the Examiner for the time and effort devoted to the interview.

Claims 1-5, 12, 19, 21-23, and 30 have been rejected under 35 U.S.C. 102(e) over Diederich. For the reasons set forth below, Applicants traverse this rejection.

Diederich is directed to a circumferential ablation device assembly. Referring to Fig. 4 of Diederich, which is reproduced below and modified by Applicants, an ablation element 160 is provided around an expandable member 170. The expandable member 170 is attached to a catheter 101 and a guide wire 102, by which the expandable member is guided through the left atrium to the pulmonary vein. When the expandable member is positioned at the ostium of the pulmonary vein, it is expanded so that the ablation element 160 contacts the inner surface of the pulmonary vein. Upon such surface to surface contact, electrical signals are sent to the ablation element in order to form a conduction block at the pulmonary vein ostium. The conduction block can treat atrial arrhythmia by blocking the path of electrical pulses traveling through the pulmonary vein. *See col. 15, line 42 to col. 16 line 56, and col. 19, line 54 to col. 20 line 8.*



Claim 1 recites "manipulating the prosthesis to a second configuration different from the first configuration to exert a compressive force on the mitral valve annulus." Diederich does not teach or suggest exerting a compressive force on the mitral valve annulus by manipulating the expandable member 170. Referring to Fig. 4 of Diederich as shown above, the left atrium is shown with the pulmonary veins and the mitral valve. The expandable member 170 is positioned in the ostium of any one of the adjacent pulmonary veins and expanded as described above. However, the expandable member is not advanced through the coronary sinus and is not positioned so as to have any effect on the mitral valve. Therefore, applicants believe that expanding the expandable member 170 cannot exert a compressive force on the mitral valve

annulus as asserted in the Office action because the expandable member 170 is at the ostium of the pulmonary vein and not in the coronary sinus or near the mitral valve.

Furthermore, claim 1 recites " assessing mitral valve regurgitation in response to the monitoring step." However, Diederich does not teach or suggest assessing mitral valve regurgitation. The treatment described in Diederich and the device used for the treatment is for creating a circumferential conduction block at the ostium of the pulmonary vein in order to block electrical conduction along the longitudinal axis of the pulmonary vein wall and into the left atrium in order to treat atrial arrhythmia. *See col. 11, line 66 to col. 12 line 5.* Accordingly, the treatment steps described in Diederich has no bearing on mitral valve regurgitation or assessing mitral valve regurgitation based on monitoring hemodynamic function. Therefore Applicants believe that Diederich fails to teach or suggest assessing mitral valve regurgitation in response to the monitoring of hemodynamic function.

For the foregoing reasons, Applicants believe that claim 1 and dependent claims 2-18 are patentable over Diederich.

Claim 19 recites "a method of remodeling a mitral valve annulus to reduce mitral valve regurgitation." In contrast, the method disclosed in Diederich is directed to treating atrial arrhythmia by circumferential ablation of tissue at the ostium of the pulmonary vein. Furthermore, claim 19 recites "manipulating the prosthesis from the first configuration toward a second configuration for exerting a compressive force against the mitral valve annulus to reduce mitral valve regurgitation." Claim 19 also recites "assessing the degree of regurgitation in response to the monitoring step." For the reasons set forth above regarding patentability of claim 1 over Diederich, Applicants believe that claim 19 and dependent claims 20-37 are patentable over Diederich.

Claims 6-11 and 24-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Wright (U.S. Patent No. 5,522,884). Claims 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Grimes (U.S. Patent No. 6,312,447). Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Purdy et al. (U.S. Patent No. 5,562,729). Claims 14 and 32 are

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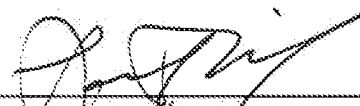
rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Fowler, Jr. et al. (U.S. Patent No. 5,086,776). Claims 15 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Killman (U.S. Patent No. 5,846,198). Claims 16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Mehta (U.S. Patent No. 5,476,453). Claims 17 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of McIntyre (U.S. Patent No. 5,291,895). Claims 18, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diederich et al. in view of Kadhiresan (U.S. Patent No. 5,935,081).

Because claims 1 and 19 are patentable over Diederich, Applicants believe that the above-noted claims are also patentable over Diederich in view of the noted secondary references.

Applicants believe that the claims are now in condition for allowance.

Respectfully submitted,
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By


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